

From: [Burkholder Kurt](#)
To: [Lori Cora/R10/USEPA/US@EPA](#)
Cc: [ANDERSON Jim M](#); [Eric Blischke/R10/USEPA/US@EPA](#); [Chip Humphrey/R10/USEPA/US@EPA](#)
Subject: Further Question on ARARs Clarification
Date: 03/30/2010 09:37 AM

Jim, here's my view on Lori's followup. Let us know if you see it differently.

First part is correct -- the acceptable risk level (ARL) and hot spots criteria are separate and distinct requirements.

Second part might be overbroad -- neither ARL nor hot spots can be applied in a vacuum in relation to other cleanup rules. For example, whether ARL is exceeded at a particular facility is determined by a risk assessment, which in turn must be based on existing and reasonably likely future exposures.

This doesn't mean, however, that the ARL and hot spots are not self-standing ARARs for CERCLA purposes. I sense that the premise underlying Joan Snyder's question is that a state standard cannot be applied as an ARAR unless someone first runs a risk assessment through a hypothetical state process to see whether the standard would be exceeded -- in effect, a shadow process to EPA's risk assessment. I don't believe that's what the NCP contemplates.

-----Original Message-----

From: Cora.Lori@epamail.epa.gov [mailto:Cora.Lori@epamail.epa.gov]
Sent: Tuesday, March 30, 2010 9:04 AM
To: Burkholder Kurt
Cc: ANDERSON Jim M; Blischke.Eric@epamail.epa.gov;
Humphrey.Chip@epamail.epa.gov
Subject: Re: Further Question on ARARs Clarification

Thanks, Jim and Kurt. Regarding the state's risk level and hot spot criteria, is it correct to say that those criteria are separate and distinct requirements for cleanup decision-making under the state's cleanup law, and the regulations themselves do not qualify or limit the application of those requirements based on the application of any other regulatory provision?

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Further Question on ARARs Clarification

Burkholder Kurt

to:

ANDERSON Jim M, Lori Cora

03/30/2010 08:54 AM

A couple further points on Joan's second question, Jim. (1) While she questions how DEQ's acceptable risk level and hot spots criteria can be applied without going through a DEQ process, she doesn't disagree they are ARARs. (2) DEQ's rules allow deterministic as well as probabilistic assessments -- another reason one cannot assume DEQ's process is less conservative and thus undermines application of the ARARs.

-----Original Message-----

From: ANDERSON Jim M
Sent: Monday, March 29, 2010 1:55 PM

To: cora.lori@epamail.epa.gov; BURKHOLDER Kurt
Subject: FW: Further Question on ARARs Clarification

Lori,

Kurt & I discussed Joan Snyder's questions re: State ARARs, & we thought it might be best for me to reply to you. For clarity, I'll summarize Joan's 2 questions (contained in her 3/9/10 e-mail to you & Kurt) & then offer a reply for you to consider.

1st Question- Should DEQ's Sediment Bioaccumulation Guidance be a TBC? I understand Joan says that our guidance applies to screening & risk assessment steps..., which have all ready been completed in the draft baseline risk assessment (BRA)..., & therefore our guidance isn't necessary. Yes, the LWG submitted a draft BRA, but their risk assessment didn't include preliminary remediation goals (PRGs) based on the food web model (FWM). The LWG stated numerous times in their draft BRA that their FWM would be submitted at a later date. We're waiting for that FWM. Two of the most important things the LWG's FWM will do is to consider bioaccumulation & back-calculate sediment PRGs from acceptable fish tissue concentrations. DEQ's Sediment Bioaccumulation Guidance contains risk-based concentrations (i.e., PRGs) that were developed using a general FWM (actually biota-sediment accumulation factors, BSAFs). The risk-based concentrations in our guidance are generic values that can be used for screening or to make cleanup decisions. Until EPA receives & accepts the LWG's FWM & associated PRGs, I think we ought to retain DEQ's Sediment Bioaccumulation Guidance as a back-up in case the LWG's FWM isn't accepted or doesn't cover all PH chemicals.

2nd Question- Is DEQ's risk assessment process essentially equivalent to EPA's process? Again, I understand Joan says that since the PH risk assessment was performed under EPA process & not DEQ's process..., Oregon acceptable risk level & hot spots rules

are

out of context & shouldn't be considered ARARs. In Joan's e-mail, she says the LWG provided specific examples of why Oregon acceptable risk levels & hot spot rules could not be applied to the output of the EPA-directed risk assessment. I assume those "specific examples" are in the LWG's 2/1/10 e-mail (with the attached "Table 1- ARAR Questions for February 4, 2010 Meeting with EPA"). The LWG's 1st specific example is that Oregon law allow the use of probabilistic risk assessment. EPA discussed using probabilistic risk assessment process with the LWG. EPA did not prohibit the LWG using probabilistic methodology. The LWG's 2nd specific example is that Oregon defines acceptable risk levels for populations of ecological receptors differently than EPA. Oregon's actual definition of acceptable risk may be more specific than EPA's, but they are essentially the same. That is, population-level protection for non-threatened-or-endangered (T&E) species, & protection of individual T&E-species receptors. The LWG's 3rd specific example is Oregon's 10⁻⁶ risk level applies only to individual carcinogens, in the case of PCBs meaning individual congeners. Joan is correct. DEQ's process for considering carcinogenic risk from PCBs is that if you have congener data, we apply the acceptable risk level for individual carcinogens to individual PCB congeners. However, if you have only total PCB data (Aroclors), then we apply the acceptable risk level for individual carcinogens to the total concentration, with the assumption that the risk could be driven by a single congener. We have consistently applied these approaches for the last ten years. The LWG's 4th & final example is that human exposure assumptions would be different under Oregon law as compared to those directed by EPA. The difference shouldn't be very significant for the PH project.

In her 3/9/10 email, Joan states that her 2nd question may not be an insurmountable problem & that Joan recommends the LWG & EPA technical teams continue to discuss this 2nd question & attempt to resolve..., or at least better understand & frame the issues at a technical level. We support Joan's recommendation.

Jim Anderson

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-----Original Message-----

From: Cora.Lori@epamail.epa.gov [
mailto:Cora.Lori@epamail.epa.gov]

Sent: Tuesday, March 23, 2010 4:59 PM

To: Burkholder Kurt

Cc: Blischke.Eric@epamail.epa.gov;
Humphrey.Chip@epamail.epa.gov

Subject: Fw: Further Question on ARARs Clarification

Hi, Kurt. Is the state going to get back to Joan on these questions?

Can you let us know what the answers will be first?
Thanks.

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----- Forwarded by Lori Cora/R10/USEPA/US on
03/23/2010 05:01 PM -----

Further Question on ARARs Clarification

Snyder, Joan

to:

Lori Cora, Burkholder Kurt

03/09/2010 04:40 PM

Cc:

jworonets, rjw, jim.mckenna, agladstone,
"Albrich, Elaine",

Chris.Reive, david.ashton, gerald.george,
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jkincaid, john.ashworth, kfavard, kims,

kpeterson, krista.koehl,

ldunn, Lparetchan, max, mwschneider, nklinger,
NvanAelstyn,

Paul.Hamada, pdost, "Snyder, Joan", sparkinson,
sriddle, tgold,

willette.a.dubose, wjoyce

Lori and Kurt,

I've been tasked with following up with you on two
items relating to

State ARARs in Lori's February 10 letter.

The first of these is a question with respect to the
designation of

DEQ's 2007 Guidance for Assessing Bioaccumulative
Chemicals of Concern

in Sediment as a TBC. In the LWG request for
clarification on February

1, we asked for clarification as to what specifically
EPA believed

should be considered that was not already considered.
In response, you

explained that:

"EPA discussed with DEQ the LWG's requested
clarification. By its

terms, the DEQ guidance may inform cleanup
levels in addition to

risk assessment. For example, we envision DEQ's
guidance could be

used for any possible chemicals not considered
in the Portland

Harbor food web model."

We are not sure we understand what this means and,
because this guidance

document applies to screening and risk assessment, and
we have already

submitted to EPA our draft risk assessments, we think
it is important to

make sure we understand exactly what you mean.

DEQ's 2007 Guidance for Assessing Bioaccumulative
Chemicals of Concern

in Sediment:

"describes a process used by the Oregon
Department of

Environmental Quality (DEQ) to evaluate
chemicals found in

sediment for their potential contribution to risk as a result of

bioaccumulation. It is presented here as an example of a method

that others may use for that purpose, if appropriate. Its use,

however, is not required." (Guidance, page 1)

Our risk assessors feel that they have used an equivalent process and

that these steps have therefore already been fully considered.

Specifically, although the guidance focuses mostly on screening steps

based on sediment screening level values (SLVs), it also explains what

to do after the comparison to SLVs:

"If the BCOI concentration is still greater than its site-specific

SLV, do one of the following:

"a. Evaluate the feasibility of cleaning up areas exceeding SLV

levels to the site-specific SLV or to ND, whichever is higher, or,

for a naturally occurring chemical, to its background

concentration ***

"or

"b. Collect data on the concentration of BCOIs in fish or benthic

invertebrate tissue using one of the following methods, and then

continue with Step 5.

"i. Collect existing tissue data from an area that is

applicable to your site (e.g., has appropriate fish home range and

analytes) or data from fish caught or benthic invertebrates

collected at your site for this purpose; or

situ bioaccumulation "ii. Perform laboratory or in

tests on sediment from the site.

measured "5. Compare the estimated or

concentration of each BCOI in fish or benthic invertebrate tissue

to appropriate acceptable tissue levels (ATLw and ATLh) or

critical tissue levels (CTL). If the concentration is lower, no

further action is required with respect to bioaccumulation for

that COI and you should continue with a regular toxicity

evaluation. If the BCOI concentration is greater than the ATL or

CTL, the COI must be considered a chemical of potential concern

(COPC) with respect to bioaccumulation and must be cleaned up to a

bioaccumulation-based level or to ND, whichever is higher; or, for

a naturally occurring compound, to its background concentration."

The guidance document applies to screening and risk assessment steps,

which have already been completed and submitted in draft to EPA. The

LWG doesn't see any issue here, because its Human Health and Ecological

risk assessors believe they have performed the equivalent of the steps

quoted above in the HHRA and the BERA and in the development of the

sediment PRGs and that this approach has therefore already been fully

considered. Does EPA have a different view?

Our second issue regarding State ARARs is really a comment relating to

the Oregon Environmental Cleanup Law, under which EPA identified both

the acceptable risk levels and hot spot rules as ARARs. With respect to

both of these, the LWG agreed they were ARARs but expressed its

understanding that any particular criteria or requirement associated

with these rules would be applied in the context of the Oregon Cleanup

Law and implementing rules as a whole. By that we meant that you need

to compare apples to apples--when applying these Oregon requirements as

ARARs, you need to apply them to the output of a risk assessment as it

would be done under Oregon law. In the LWG request for clarification,

we provided specific examples of why those criteria could not be applied

directly to the output of the EPA-directed risk assessment because the

EPA risk assessment was done differently, and likely more

conservatively, than it would have been done under Oregon

law-essentially apples and oranges.

The response you provided was that "DEQ considers the risk assessment

performed by the LWG to be generally consistent with what DEQ would

require under its program, and adequate for determining whether

acceptable risk levels are exceeded at the site." We don't disagree

that the EPA risk assessment is adequate under Oregon law. However, we

do believe it is likely more conservative, which causes the apples and

oranges problem if you try to apply the acceptable risk criteria or the

hot spot rules directly to the output of the EPA-directed risk

assessment.

We do not think this is an insurmountable problem. Our technical teams

are having discussions on risk and hot spots and trying to work with the

output of the EPA directed risk assessment. We think it is most

productive for these conversations to continue on the technical level.

However, when we get to the point in the future of trying to determine

what it means to apply Oregon acceptable risk rules or Oregon hot spot

rules as ARARs, we believe that discussion will need to come back to an

apples-to-apples comparison. We are hoping that the technical

discussions will help us understand how to best make those comparisons.

Thanks for your input on these issues.

Joan P. Snyder

Chair -- Resources Development and Environment Group

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